§ 900.5 Evaluation.

FDA will evaluate annually the performance of each approved accrediting body by:

(a) Inspecting a sample of the facilities accredited by the body and evaluating the reports of inspections to ascertain whether the facilities accredited by the accrediting body are in compliance with the standards promulgated by the agency in subpart B of this part, and

(b) Evaluating a sample of the body's clinical image and phantom image reviews, evaluating the body's speed and efficiency in accrediting facilities, evaluating the body's ability to file reports within deadlines, and reviewing the body's records and recordkeeping processes.

§ 900.6 Withdrawal of approval.

If FDA determines, through the evaluation activities of § 900.5 or through other information that comes to the attention of the agency, that an accrediting body is not in substantial compliance with this subpart, FDA shall initiate enforcement actions as follows:

(a) *Major deficiencies.* If FDA determines that the accrediting body has major deficiencies in performance, such as commission of fraud, or material false statements, or failure to perform a major accreditation function satisfactorily, or significant noncompliance with the requirements of this subpart A, FDA will withdraw its approval of that accrediting body and notify such body of the grounds on which the approval was withdrawn.

(b) *Minor deficiencies.* If FDA determines that the accrediting body has minor deficiencies in the performance of an accreditation function, including minor failure to comply with this subpart A, FDA will notify the body that it has 90 days to submit to FDA a plan of corrective action addressing the problems specified by FDA. This plan must include a summary of planned corrective actions and a schedule for their implementation.

(1) If the corrective action plan is received within the 90-day time period specified and is satisfactory to FDA, FDA will notify the body that it is on probationary approval status until further notice. This probationary status will remain in effect until such time as the body can demonstrate to the satisfaction of FDA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective actions taken have substantially eliminated all identified problems. When such determination of restoration of satisfactory performance is made, FDA will restore the body to full approval status.

(2) If the body does not submit a satisfactory corrective action plan within the designated 90-day time period or does not implement an FDA-approved corrective action plan within the time interval specified in the corrective action plan (as amended, with FDA approval, if necessary) FDA will withdraw approval of the body as an accrediting body. In cases of withdrawal of approval of accrediting bodies, if FDA finds that there are satisfactory assurances that the unacceptable performance of the accrediting body has been substantially resolved, on application by the accrediting body, FDA may reinstate the approval of the accrediting body, unless there have been fraud or material false statements.

§ 900.7 Hearings.

Opportunities to challenge final adverse actions taken by FDA regarding approval of accrediting bodies, withdrawal of approval of accrediting bodies, or rejection of a proposed fee shall be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

Subpart B—Quality Standards and Certification

SOURCE: 58 FR 67570, Dec. 21, 1993, unless otherwise noted.

§ 900.10 Applicability.

The provisions of this subpart are applicable to all facilities under the regulatory jurisdiction of the United States that provide screening and/or diagnostic mammography services, with the exception of facilities of the Department of Veterans Affairs.